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HEADLINE: Time Not on **Biopure's** Side

BYLINE: By Adam Feuerstein , Senior Writer; Adam Feuerstein writes regularly for RealMoney.com. In keeping with TSC's editorial policy, he doesn't own or short individual stocks, although he owns stock in TheStreet.com. He also doesn't invest in hedge funds or other private investment partnerships. He invites you to send your feedback.

BODY:

This is a bonus column from Adam Feuerstein, whose commentary usually runs only on RealMoney. We're offering it today to TheStreet.com readers. To read Adam's commentary every day, click here for information on a free trial to RealMoney.

In two-plus years following **Biopure** (BPUR:Nasdaq) and its faulty experimental blood substitute Hemopure, I've been most surprised about one thing: the capacity for some investors to remain bullish despite the weight of evidence to the contrary.

After the torrent of bad news released by the company Thursday, I wonder how even the most obstinate of **Biopure** bulls could have any confidence left at all. The credibility of **Biopure** management is in question, and the odds of Hemopure's eventual approval seem more remote than ever before.

Thursday, **Biopure** acknowledged that it would be unable to respond until the end of June 2004 to the Food and Drug Administration's request for additional information on Hemopure -- a significant delay. The company also fired Howard Richman, its top regulatory executive in charge of the Hemopure filing, and announced large-scale layoffs and cost-cutting because its bank account empties out in June.

All this bad news sent **Biopure** shares tumbling Thursday \$2.37, or 39%, to \$3.68

That's a tough break for **Biopure** shareholders, who have loyally kept the stock price up despite years of disappointing delays. One shareholder, however, who has done well recently is **Biopure** co-founder, former CEO and current CTO Carl Rausch, who was able to sell more than \$1 million worth of his **Biopure** holdings this summer when the stock was trading in the \$7 range.

Biopure has said that Rausch's stock sales were not related at all to Hemopure's regulatory situation. But today's announcement, coupled with Rausch's insider status, should raise new concerns about the timing of these stock sales.

Biopure executives did not return a phone call Thursday seeking further comment.

Let's address the FDA timeline, first. June seems a long way off, especially compared to the confident tone management took last Aug. 1, when it announced -- rather triumphantly -- that the FDA had completed its Hemopure review, but had requested a bit more clinical information before it could issue a final decision. At that time, CEO Tom Moore told the Boston Globe that a response to the FDA would take one or two months

to compile. Later, as fall rolled around, that timeline from **Biopure** stretched to three or four months.

Now, **Biopure** says that it will take 11 months from the receipt of its FDA response letter to provide the agency with the information requested.

Back in those heady days of August, **Biopure** management assured that its relationship with the FDA couldn't be better. The company insisted that regulators actually completed its Hemopure review one month earlier than expected, and that it would take just 30 days to issue a final decision on the product (a hint that it likely would approve it) once it had a chance to go over the new Hemopure data.

Thursday, Moore acknowledged that the FDA would in fact take a lot longer than one month to issue a decision. It will likely take at least six months, possibly even longer, Moore now says.

This means that if **Biopure** can meet its new June 30 deadline for an FDA resubmission, an answer from regulators wouldn't come until the end of December 2004. But how can anyone have any confidence in **Biopure's** timeline? The June 30 date seems entirely arbitrary, because the company admitted yesterday that collecting all the data requested by the FDA will be a time-consuming and arduous task. **Biopure** doesn't even know if all the data is collectable. And no one knows how long the FDA will really take to respond. Six months? Twelve months? Longer?

Why was Howard Richman fired from **Biopure**? **Biopure** said in its press release that he left the company to "pursue other interests." But on its conference call Thursday morning, CEO Moore said, "Let's just say that he didn't choose to leave us, per se."

Richman was **Biopure's** senior vice president of regulatory affairs, and as such, was the primary point person dealing with the FDA. He, more than any other **Biopure** executive including Moore, was in a position to understand the full extent of the agency's feelings about Hemopure and likely knew more than anyone how much work would be required to compile the information requested by regulators.

But Thursday, **Biopure** tells us that Richman was fired, and at arguably the most critical juncture in the company's history. Moore offers no explanation for the firing. The company has retained an outside consultant, David Zuchero, to take up the regulatory slack, but he's coming into a red-hot situation ice cold.

When did **Biopure** really know that the work ahead of it on Hemopure was going to be far more daunting than it first realized? It's an important question, given the company stock sold by insiders, including former CEO Rausch, during the summer months.

On the conference call Thursday morning, Moore said the Hemopure review letter sent by the FDA to the company on Aug. 1 contained "language that was, quite frankly, confusing to us."

At other times during the conference call, Moore acknowledged that the company knew the FDA's information request was going to be time-consuming, but that it was negotiating for short cuts, which ultimately failed.

But if the company had come clean about its timelines in August, when it first heard back from regulators, the company's stock price likely would be closer to today's level than the \$7 to \$8 range it traded at over the summer.

The higher price benefited **Biopure** insiders selling stock. On various dates from Aug. 5 through Aug. 28, while CEO Moore was telling investors how well the FDA review was progressing, Rausch sold 149,500 shares of **Biopure** common stock, at prices ranging from \$7 to \$8 per share, with net proceeds exceeding \$1.1 million. Moore also sold some company stock, as did members of the board of directors.

On its fiscal third-quarter conference call of Aug. 21, Moore addressed the issue of insider selling, saying, "Our co-founder and Chief Technology Officer Carl Rausch is continuing to sell a relatively small portion of his **Biopure** holdings in order to meet his personal financial needs. He publicly announced his intent to do so, in

fact, some time ago."

Finally, **Biopure**, once again, is desperately short of cash. Even with the layoffs and cost-cutting announced Thursday, the company only has enough cash to last through May or June. **Biopure** is trying to renew an equity stand-by agreement that would allow it to sell another \$15 million in stock to the public. If successful, the new cash would last through December 2004.

Who would actually buy **Biopure** stock right now? Short-sellers and arbitragers, of course, because it's an easy way of covering at least a portion of their short sales and pocketing instant profits. "**Biopure** is like an ATM," one short-seller joked to me today.

Biopure longs, especially retail investors, should keep this in mind before they argue how **Biopure's** continuing ability to raise cash represents some sort of validation and confidence in its blood substitute.

In fact, **Biopure** could be living on borrowed time. In some perverse way, it actually benefits the company to drag out its FDA response as long as possible, so don't be surprised to see the new June deadline get extended once again. Right now, **Biopure** controls the clock, but once it responds to the FDA, regulators gain control, and that might finally bring this long, sad story to an end.

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